



Government of the District of Columbia

Department of Health
Health Regulation and Licensing Administration
Pharmaceutical Control Division



NON-RESIDENT: DRUG MANUFACTURE AND DISTRIBUTION

*To expedite the processing of your **NEW / RENEWAL** licensure application, **submit all items on the application checklist below.***

CHECKLIST

- ___ \$100 Registration biennial Fee in the form of check or money order made payable to DC Treasurer. §22-404.3
- ___ A completed and signed DC application form. §22-404.4(a)
- ___ Proof of current approval by the US Food and Drug Administration. (Manufacturers only) §22-404.3(c)
- ___ Proof of current US Drug Enforcement Administration (DEA) Registration if business activities include controlled substance. §22-404.4(d)
- ___ Signed Clean Hands form. §47-2861
- ___ List trade or business names of applicant and the address and telephone number of the place of business for which the applicant seeks a license. §22-404.6
- ___ A Certificate of good standing in the state where incorporated or where the principal place of business is located (if applicable) §22-404.3(b)
- ___ List name, address and telephone number of all corporate officers/partners. §22-404.6
- ___ A copy of your current corporate registration, along with corporate articles of incorporation. §22-404.6
- ___ List the name, address, and telephone number of contact personnel for all facilities. §22-404.6
- ___ Detailed description of the activity for which the applicant seeks a license. §22-404.6
- ___ List of all drugs that the applicant proposes to manufacture, distribute, or wholesale in the District of Columbia. §22-404.6
- ___ Copy of the most recent inspection report (if applicable). §22-404.6



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- ____ Email address and fax number for facility. §22-404.6
- ____ Completed Controlled Substances application (if applicable), accompanied by \$130 for the in the form of check or money order made payable to DC Treasurer.
- ____ A complete list of DC Resident Agents who can receive official documentation on behalf of licensee. (www.registered-agent-listings.com) §22-404.6
- ____ A Certificate of Occupancy for the facility (if applicable). §22-404.6
- ____ Does the facility provide compounding as a service for their customers? (Yes/No)

Additional References:

- DC Drug Manufacturer and Distribution Licensure Act (D.C. Law 8-137)
- (D.C. Official Code Title 48, Chapter 7) and D.C. Municipal Regulations, Title 22, Chapter 4 is on the website [Laws and Regulations](#)

**NB: MAIL COMPLETED APPLICATION AND PAYMENT TO: DOH – Pharmacy
P.O. Box 37803
Washington D.C. 20013**